

**DETAILED ACTION**

**EXAMINER'S AMENDMENT**

**1.** An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Matt Buchanan on October 5, 2009.

The application has been amended as follows:

**Claims** 1-7 have been cancelled.

**Claim** 8. (Currently amended) A valve prosthesis for implantation within a vascular vessel, comprising:

a support frame supporting two or more leaflets, the two or more leaflets including a coaptation position and cooperatively forming a valve orifice, at least a portion of the support frame supporting each of the two or more leaflets at a point adjacent the valve orifice;

each of the two or more leaflets including opposing proximal and distal leaflet surfaces and first and second outer edges;

the support frame and leaflets together functional as a valve to restrict blood flow in a first direction when implanted in the vascular vessel;

Art Unit: 3774

the support frame comprising frame elements around which the first and second outer edges of the two or more leaflets are wrapped to allow the first and second outer edges of each of the two or more leaflets to non-circumferentially engage a wall of the vascular vessel such that the frame elements are non-centering of the co-aptation position within the vascular vessel; and

at least one centering support element configured to center the co-aptation position within the vascular vessel, each of the at least one centering support element attached to the frame elements only at one or more points adjacent the two or more leaflets and including a portion that traverses one of the two or more leaflets from the first outer edge to the second outer edge and is free of contact with the proximal leaflet surface and the distal leaflet surface of one of the two or more leaflets;

wherein the support frame comprises a first serpentine section having first and second opposing bends positioned at a first end of said valve prosthesis and third and fourth opposing bends positioned at a second, opposite end of said valve prosthesis, said first and second opposing bends lying on a first transverse axis of said valve prosthesis and said third and fourth opposing bends lying on a second transverse axis of said valve prosthesis;

**wherein the at least one centering support element comprises a centering support frame comprising**~~[wherein the at least one centering support element comprises]~~ a second serpentine section having fifth and sixth opposing bends positioned at the first end of said valve prosthesis and seventh and eighth opposing bends positioned at the second, opposite end of said valve prosthesis, said fifth and sixth opposing bends lying on a third transverse axis of said valve prosthesis and said seventh and eighth opposing bends lying on a fourth transverse axis of said valve prosthesis;

Art Unit: 3774

wherein the first transverse axis is substantially perpendicular to the second transverse axis and the third transverse axis is substantially perpendicular to the fourth transverse axis; [and]

wherein the first transverse axis is substantially perpendicular to the third transverse axis and the second transverse axis is substantially perpendicular to the fourth transverse axis;

**wherein each of the support frame and the centering support frame are discrete structures interconnected at two or more points; and**

**wherein the opposing bends at the first and second ends of the support frame are the only bends in the first and second ends of the support frame.**

**Claims** 12-15, 19, 23-26, 30-35, and 37-39 have been cancelled.

**Claim** 40. (New) The valve prosthesis of claim 8, wherein the support frame and the centering support frame are formed from a cannula.

**Claim** 41. (New) The valve prosthesis of claim 40, wherein the cannula comprises metal.

**Claim** 42. (New) The valve prosthesis of claim 41, wherein the metal comprises stainless steel.

**Claim 43.** (New) The valve prosthesis of claim 41, wherein the metal comprises nitinol.

**Claim 44.** (New) The valve prosthesis of claim 8, wherein the support frame and the centering support frame are formed from wire.

**Claim 45.** (New) The valve prosthesis of claim 44, wherein the wire comprises rounded wire.

**Claim 46.** (New) The valve prosthesis of claim 44, wherein the wire has a cross-sectional shape selected from the group consisting of oval-shaped, delta-shaped, and D-shaped.

**Claim 47.** (New) The valve prosthesis of claim 44, wherein the wire comprises flat wire.

**Claim 48.** (New) The valve prosthesis of claim 8, wherein the support frame and the centering support frame are interconnected by a short strut.

**Claim 49.** (New) The valve prosthesis of claim 8, wherein the two or more leaflets comprise a biomaterial.

Art Unit: 3774

**Claim 50.** (New) The valve prosthesis of claim 49, wherein the two or more leaflets comprise a remodellable material.

**Claim 51.** (New) The valve prosthesis of claim 49, wherein the two or more leaflets comprise an extracellular matrix material.

**Claim 52.** (New) The valve prosthesis of claim 51, wherein the extracellular matrix material is selected from the group consisting of small intestine submucosa, pericardium, stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa, and dura mater.

**Claim 53.** (New) The valve prosthesis of claim 51, wherein the extracellular matrix material comprises small intestine submucosa.

**Claim 54.** (New) The valve prosthesis of claim 49, wherein the two or more leaflets comprise elastin or elastin Like Polypeptides (ELPs).

**Claim 55.** (New) The valve prosthesis of claim 49, wherein the two or more leaflets comprise harvested native valve tissue.

Art Unit: 3774

**Claim 56.** (New) The valve prosthesis of claim 8, wherein the two or more leaflets comprise a synthetic material.

**Claim 57.** (New) The valve prosthesis of claim 56, wherein the synthetic material comprises DACRON or expanded polytetrafluoroethylene (ePTFE).

**Claim 58.** (New) The valve prosthesis of claim 8, wherein the two or more leaflets comprise two leaflets.

**Claim 59.** (New) The valve prosthesis of claim 8, the first and second outer edges of the two or more leaflets are wrapped around obliquely opposite frame elements.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to

Art Unit: 3774

the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/David H Willse/

Primary Examiner, Art Unit 3738